

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**20-297/S-009**

**Correspondence**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-297/S-009

Smith Kline Beecham Corporation d/b/a GlaxoSmithKline  
Attention: Ms. Catherine Clark  
One Franklin Plaza  
P.O. Box 7929  
Philadelphia, PA 19101-7929

Dear Ms. Clark:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Coreg (carvedilol) tablets  
NDA Number: 20-297  
Review Priority Classification: Priority (P)  
Supplement number: S-009  
Date of supplement: September 27, 2002  
Date of receipt: September 27, 2002

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act November 26, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Cardio-Renal Drug Products,  
HFD-110  
Attention: Division Document Room  
5600 Fishers Lane  
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Cardio-Renal Drug Products  
HFD-110  
Attention: Division Document Room 5002  
1451 Rockville Pike  
Rockville, Maryland 20852

NDA-20-297/S-009  
Page 2

If you have any question, call me at (301) 594-5333.

Sincerely yours,

A handwritten signature in black ink, appearing to be the initials 'ZM' or 'ZM/CD'.

Zelda McDonald  
Acting Chief, Project Management Staff  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Zelda McDonald  
10/17/02 04:12:56 PM